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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2009* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,22-38 and 42-47* is/are pending in the application.

4a) Of the above claim(s) *34-38 and 43-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-33 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 01/13/2009; and the drawing filed 03/04/2009.

Claims 22-38, and 42 are previously presented. Claims 34-38 are withdrawn from further consideration as being directed to non-elected invention.

Claims 43-37 are currently added.

Claims 2-38 and 42-47 are pending.

Election/Restrictions

1. Newly submitted claims 43-47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are directed to composition comprising crosslinked gelatin, wetting agent and saline solution, while instant claim 22 does not require saline solution, rather require non-aqueous solvent. Additionally, claims 44-47 require syringe assembly having specific structure that is not required by the composition of claim 22-33, and 42. Invention of claims 22-34 and 42 and invention of claims 43-47 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together because invention of claim 22 -34 and 42 does not require the syringe assembly that is required by invention of claims 43-47. Even the hemostatic composition of claim 22 is distinct from the composition of claim 43 as claim 22 requires non-aqueous solution and claim 43 require aqueous solution. Therefore, the inventions as claimed have different designs, and consequently different modes of operation, and effects.

2. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43-45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 22-33 and 42 are included in the prosecution.

Specification

4. The amendment filed 01/13/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: amendment made to paragraph 0053 to describe figure 1 that is added by the amendment filed 03/04/2009 introduced new matter because it is not known if figure 1 is the original assembly applicant invented. Paragraph 0053 does not describe that the sterile saline is added through side tube 12, only describe saline is added. Further paragraph 0053 does not describe the relation of the parts together to assure that the drawing submitted on 03/02/2009 was original, for example the position of the cannula 24 in relation to the ejection port 22 is not clear from reading paragraph 0053.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 22-33, 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims as amended to recite: "a non-aqueous solvent is used to dissolve the wetting agent" has introduced new matter. Nowhere applicants disclosed that the biocompatible hemostatic composition comprises a non-aqueous solution. Applicants refer to paragraph 0122 for support. Paragraphs 0121 and 0122 state that: "[0121] The above data demonstrates that there is no appreciable difference in the hydration time of the coated cross-linked gelatin using different solvents to coat the gelatin. [0122] However, the solvent employed should be non-aqueous to the extent that water irreversible damages the foam." The data applicants are referring to is the hydration time of compositions of dried gelatin coated with wetting agent. Non-aqueous solvent used for the purpose of measuring hydration time of compositions having different wetting agents. Applicants themselves admit that the data demonstrates that there is no appreciable difference between aqueous and non-aqueous solvent in the hydration time of the coated cross-linked gelatin. In

accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 22-29, 31 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 02-182259 (259) in view of EP 5568 334 ('334).

JP '259 teaches composition comprising cross linked gelatin, and solution comprising surfactant impregnated into the cross linked gelatin (see the provided abstract). The composition comprises 1-50 % of gelatin in aqueous solution and from

0.1 % to 30 % of the aqueous solution is the surfactant (page 5, last paragraph; page 6, first full paragraph). The reference disclosed in the process of making the composition, the gelatin solution is prepared, then, the surfactant is added followed by foaming and drying, i.e. evaporation of the solvent (page 6, second full paragraph; page 10, operational example 1). The composition easily dissolves in blood or body fluids, i.e. bioabsorbable (page 7, third line). The surfactants disclosed by the reference include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph). The material disclosed by the reference that comprises cross-linked gelatin and the same wetting agent, is expected to decrease the hydration time of the cross-linked gelatin that claimed in claim 22. Furthermore, on page 5, lines 25-27 of the present disclosure, applicants disclosed that the hydration time is the time needed to prepare the gelatin for use, and the reference disclosed on page 11, third full paragraph that hemostatic composition showed slight swelling and arrested bleeding in 60 seconds, i.e. the composition was ready for use.

The difference between JP ‘259 and the present invention is that JP ‘259 does not explicitly teach non-aqueous solvent in the composition as required by claim 22. JP ‘259 does not teach that the composition comprising growth factor as instantly claimed claim 31.

EP ‘334 teaches collagen containing sponge comprising cross linked gelatin and active agent, preferably growth factors which enhanced wound healing and nerve regeneration (abstract; col.5, lines 22-30). The composition disclosed by EP ‘334 comprises drying enhancer to accelerate the drying time of the composition, and

disclosed that ethanol is preferred drying enhancer (col.4, lines 56-59; col.10, claims 8 and 9).

Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to provide hemostatic composition comprising cross linked gelatin and wetting agent as disclosed by JP ‘259, and further add ethanol to the composition as taught by EP '334. One would have been motivated to do so because EP ‘334 teaches that ethanol is a preferred drying enhancing agent that accelerates drying of hemostatic composition. One would reasonably expected formulating hemostatic composition comprising cross linked gelatin, wetting agent and ethanol that dries fast on the bleeding site to enhance hemostasis. Additionally, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide hemostatic composition comprising cross linked gelatin and wetting agent as disclosed by JP ‘259, and add growth factors to the composition as disclosed by EP ‘334. One would have been motivated to do so because EP '334 teaches that growth factors are preferred active ingredient to be added to hemostatic wound treating composition comprising gelatin because growth factors enhance wound healing and nerve regeneration. One would reasonably expected formulating composition comprising cross linked gelatin, wetting agent and growth factors wherein the composition enhances wound healing and nerve regeneration successfully.

10. Claims 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 combined with EP '334, and further in view of US 6,063,061 ('061).

The combined teachings of JP '259 and EP '334 are previously discussed as set forth in this office action.

However, JP '259 does not teach that the composition is sterilized and packaged as claimed by claim 30, or the composition comprising thrombus enhancing agent as claimed in claim 32, or antimicrobial agent as claimed in claim 33.

US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin, plasticizer and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition further comprises active agent such as antibiotics and hemostatic agents including thrombin and clotting factors (col.11, lines 16-35). The composition can be in the form of sterile package (col.3, lines 33-34; col.5, lines 6-10, 25-35; col.8, lines 32-36).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide the hemostatic composition comprising crosslinked gelatin, wetting agent and non-aqueous solvent disclosed by the combination of JP '259 and EP '334, and add antimicrobial and/or clotting factors as disclosed by US '061. One would have been motivated to do so because US '061 teaches that such agents are beneficial for hemostasis. One would reasonably expected formulating hemostatic composition comprises cross-linked gelatin, wetting agent, non-aqueous solvent and further comprises antimicrobial and/or clotting factors that are beneficial for hemostasis.

Additionally, one having ordinary skill in the art would have been motivated to sterilize and package the gelatin sponge produced by the combination of JP '259 and EP '334 as disclosed by US '061. One would have been motivated to do so because US '061 teaches that crosslinked gelatin composition can be sterilized safely, and further motivated by the logic of the wound dressing art that sterilization and package of gelatin material will be safer to use on the wound or bleeding site. One would reasonably expected formulating sterile packaged gelatin sponge incorporating wetting agent and non-aqueous solvent that is safe to apply to bleeding site or wound.

Response to Arguments

11. Applicant's arguments with respect to claims 22-33, 42 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that claim 22 now recites a biocompatible, hemostatic, cross-linked gelatin composition wherein "a non-aqueous solvent is used to dissolve the wetting agent." Using a non-aqueous solvent to dissolve the wetting agent provides a number of advantages not present in the Yasushi et al. reference. For example, employing an aqueous solvent to dissolve the wetting agent can irreversibly damage the foam. On the other hand, using a non-aqueous solvent to dissolve the wetting agent protects the structural properties of the foam (see [0122]). Since the Yasushi et al. reference does not appear to teach every word of amended claim 22, claim 22 is not anticipated by the cited art. Furthermore, since claims 23-29 and 42 depend from claim 22, are also patentable over the cited reference.

In response to this argument, first the examiner noticed that applicants argue that the cited art does not anticipate claim 22, while no anticipatory rejection is made in the previous office action. In view of the current rejection of claim 22 over JP '259 combined with EP '334, the invention as a whole is taught by the prior art, i.e. hemostatic composition comprising crosslinked gelatin, wetting agent and non-aqueous solvent (ethanol). In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

12. With regard to the rejection of the claims 30, 32, and 33 under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of US 6,603,061 and rejection of claim 31 under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of EP 5568 334, applicant has failed to traverse the rejections and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611